UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

MICHAEL W. HARRIS, et al.,	:	
	:	**Civil Action No. C-1-01-428**
Plaintiffs,	:	
	:	**Honorable Judge S. Arthur Spiegel**
v.	:	**Magistrate Timothy S. Hogan**
	:	
PURDUE PHARMA, INC., et al.,	:	**PLAINTIFFS' REPLY IN SUPPORT**
	:	**OF CLASS CERTIFICATION**
Defendants.	:	

I. Introduction

Plaintiffs present to the Court manageable and discrete requests for relief, seeking solely the equitable remedies of medical and prescription monitoring, and creation of a research fund. Because Plaintiffs do not seek certification of a national class action for personal injury claims, and because Plaintiffs do not seek individual compensatory damages, the complications which Defendants have attempted to heap into the record may be disregarded as irrelevant to the claims actually before the Court. Instead, Plaintiffs herein seek relief in the form of equitable remedies only, making the case simplified and manageable, and ideally suited to national resolution on a class wide basis.

The class proposed by Plaintiffs consists of those persons prescribed OxyContin, who do not assert claims for personal injury. As such, the class members are easily identifiable, because those with personal injury claims are identifiable through their court filings and may be excluded.

Finally, the existence of a class in need of relief is well established. Since the introduction of OxyContin, Defendants' unprecedented marketing efforts to promote the most powerful oxycodone product on the market has resulted in a crisis of epidemic proportions in our country. Defendants targeted OxyContin primarily to family physicians. Defendants oversold the benefits and trivialized the risk of addiction from OxyContin, particularly in the treatment of

chronic, non-malignant pain. Such wide-scale use of this powerful heroin-like drug necessarily has caused thousands of people to become dependent or addicted to this drug.

Because the OxyCOntin problem grew to epidemic proportions, the Congress and the Senate have held hearings specifically regarding OxyContin. The GAO has been asked to investigate certain issues pertaining to Purdue and its sale and marketing of OxyContin. The DEA has spent an enormous amount of time and resources on this issue as have the state Attorneys General. OxyContin has plagued not only individuals and their families, but the resources of our entire country.

II. Because Plaintiffs' Claims Are for Equitable Relief Only, This Case is Uniquely Suited for Class Certification.

Plaintiffs have excluded from the class definition any individual who seeks compensatory damages based upon personal injury.[1] Thus the only issue before the Court is Plaintiffs' claim for equitable relief. Claims for equitable relief only are tried to the Court, not to a jury. *See U.S. Const. Amend VII*. A jury is only appropriate in the context of equitable claims when Plaintiffs pursue both legal and equitable claims for relief, which share common factual issues. *See Beacon Theatres, Inc. v. Westover*, 359 U.S. 500, 510-11, 79 S.Ct. 948, 3 L.Ed.2d 988 (1959). Plaintiffs herein present no such legal claims. As such, trial by jury is unavailable and unnecessary.[2]

Because no right to trial by jury attaches to claims based solely in equity, Plaintiffs' request for a national class action for equitable relief avoids many of the manageability problems that arose in other national class action cases cited by Defendants. Certainly the

[1] In *Foister v. Purdue Pharma*, 2002 WL 1008608, plaintiffs sought certification of a Kentucky personal injury class, defined as all persons "who have been harmed" due to the addictive nature of OxyContin. Because the Court considered the class definition ambiguous, the court held that Plaintiffs failed to meet the requirements of Rule 23(a). This case does not address the propriety of certifying a national medical monitoring class action, and is therefore not binding on this court. (*See Bridgestone/Firestone Inc.*, 333 F.3d 763 (7th Cir. 2003), class certification decision entitled to collateral estoppel effect only when subsequent class involves same definition and same claims.)

[2] *But see Barnes v. Amer. Tobacco*, 161 F.3d 127, 134 (3rd Cir. 1998), wherein the court did not reach the issue of whether the trial court erred in determining that a right to trial by jury existed for medical monitoring claims.

Court can efficiently determine issues involving variations in state laws. Further, the Court may call on the parties for briefing on any specific issue that might arise in the future. Even if the Court determines that a jury trial is appropriate, Plaintiffs have submitted a carefully curtailed class definition, which avoids many of the complexities presented in certain national personal injury class action cases.

III. Plaintiffs' Claims Are Based Upon Common Theories for Equitable Relief Applicable to All Persons Prescribed OxyContin.

A. Defendants Engaged in Uniform Tortious Conduct Toward the Class.

As set forth in Plaintiffs' Complaint and Plaintiffs' Motion and Memorandum in Support of Class Action Certification, Plaintiffs seek recovery in the form of medical and prescription monitoring and establishment of a research fund on behalf of all persons prescribed OxyContin who do not separately claim personal injury. The basis for Plaintiffs' claim is simple and straightforward. Defendants have manufactured and aggressively marketed OxyContin for chronic, long-term, unsupervised use by patients to treat pain. This product contains extremely high doses of the opioid, oxycodone, a narcotic much more potent than morphine. Defendants represented to physicians and the public that patients who used OxyContin for pain relief would not become addicted, consistently stating in their marketing and promotions that persons prescribed OxyContin for pain had minimal to no risk for addiction from this drug.

Defendants, however, never conducted any studies on the long-term use of OxyContin to determine the risk of addiction from chronic use. Instead, they relied upon outdated studies of narcotic use in acute pain settings, such as in cancer wards or burn units. These cited studies all utilized hospitalized patients receiving narcotics under the supervision of their physicians, to justify their claim that patients prescribed OxyContin would not become addicted. (See discussion of these studies within Plaintiffs' Memorandum, pp.4-5). Yet these studies have no bearing upon the risks posed by introducing highly potent opioid pills to the general population for unsupervised, chronic, use. (See, e.g., Jick Depo. at pp.18, 24-25, 32-33, stating

this his data published in 1980 regarding hospitalized patients who received narcotics "doesn't tell me anything" about the level of addiction for people prescribed OxyContin. See also Ex. 9, p.8) Indeed, Defendants now admit that the level of addiction risk from OxyContin remains unknown. In the 2003 Physicians Desk Reference, Purdue states:

> Concerns about abuse, addiction, and diversion should not prevent the proper management of pain. The development of addiction to opioid analgesics in properly managed patients with pain has been reported to be rare. However, data are not available to establish the true incidence of addiction in chronic pain patients.

See Ex. 1 at pp.2852-53

Because the true risk of addiction from the long-term use of OxyContin has never been quantified, no basis exists to claim that addiction is "rare." Plaintiffs' experts, however, opine that the risk of addiction to OxyContin for persons prescribed the drug ranges from 7% to 28%. (See Plaintiffs Motion for Class Certification, January 28, 2003, at Exs. A and C.) Thus, despite Defendants' representations to the contrary, all persons prescribed this drug are exposed to a significant risk of harm through addiction. Further, the twelve-hour time-release design of the product enhances the risk of addiction, by causing a large spike of oxycodone to be released after initial ingestion. The amount of oxycodone in the drug then tapers down considerably such that the last two to three hours of the dosage contains minimal oxycodone and therefore minimal pain relief. This extremely uneven release of the product is contrary to Defendants' representation that the formulation provides continuous and consistent absorption. This tapering down of pain relief within the dosage coincided with Purdue's marketing of OxyFast and OxyIR to be sold as rescue medication for patients who needed pain relief in the last several hours of the 12-hour dosage period. Thus Defendants are strictly liable to all class members based upon their uniform conduct regarding the testing, warning and design of OxyContin, which created a uniform risk of harm to the class.

B. Abbott Laboratories Played a Crucial Role in Harming the Class.

Defendants concede that Abbott and Purdue entered a Co-Promotion Agreement for OxyContin on January 1, 1996, shortly after product introduction. (Abbott response at Ex. A.) Pursuant to the Agreement, Abbott shared handsomely in the profits on sales of OxyContin (*Id*. at 14-15), and its name and logo appeared jointly with Purdue's on all advertising and promotional materials for OxyContin. (Id. at 19). As part of the Co-Promotion Agreement, Abbott provides a sales force of at least 300 representatives throughout the United States, and bore the cost of training and supervising these sales representatives. (Id. at 9-10.) Because Abbott jointly shared with Purdue in the expenses and profits of the business venture, Defendants are jointly liable for the harm caused by the product which was the subject of their venture. See Ohio Revised Code §1775.06(D) ("the receipt by a person of the share of the profits of a business is prima facie evidence that he is a partner in the business…"); Ohio Revised Code §1775.08(A) Agent of Partnership; and see Ohio Revised Code §1775.14 (A)(1) (partners are jointly and severally liable for everything chargeable to the partnership). The parties clearly contemplated that liability to third parties could arise as a result of Abbott's participation in promoting OxyContin. In fact, they included an indemnification provision in the Co-Promotion Agreement, which requires Purdue to indemnify Abbott for any claims by third parties alleging "death, [or] personal injury". (Id. at 34.) Moreover, Abbott's liability is not merely derivative. Instead, Abbott acted on its own to aggressively market OxyContin to the class, in a manner which increased the risk of harm to class members. (See Ex. 2, FDA Warning Letter concerning misleading ad by Purdue and Abbott with ad also attached.)

Abbott's argument against certification based upon its alleged lack of culpability is a classic request for a determination on the merits. As such, the argument is improper when determining class certification. *Eisen v. Carlisle & Jacqueline*, 417 U.S. 156, (1974); *In re: Telectronics Pacing Systems Inc.*, 172 F.R.D. at 271, 282 (S.D. Ohio 1997). Other courts have rejected Abbott's arguments against certification because Abbott confuses class issues with

merits relief. See *Howland v. Purdue*, 2003 WL 21637968 (Ohio App. 12 Dist), at ¶ 38 (attached hereto as Ex. 12). To the extent that Abbott does state a defense on the merits, its argument does not defeat class certification. To the contrary, a common defense can be a basis to find certification appropriate. *Telectronics*, 172 F.R.D. at 291-292 (noting that state of the art defense is a common issue.)

C. The Monitoring Program Advocated by Plaintiffs is Recognized as a Necessary Tool to Promote Public Health.

The goal of medical monitoring is to provide equitable relief which promotes and protects the public health. Courts frequently approve monitoring programs which screen for disease or provide research into public health risks created by Defendants' wrongful conduct. See *St. Jude Medical Inc.*, 2003 WL 1589527 (D. Minn.) (certifying nationwide medical monitoring class for persons implanted with Silzone prosthetic heart valves); (attached hereto as Ex. 12), *In re: Diet Drugs*, 1999 WL 673066 (E.D. Pa.) (certifying nationwide medical monitoring class for persons who ingested diet drugs); *In re: Telectronics*, 172 F.R.D. 271 (S.D.Ohio 1997). See also *Day v. NLO*, 851 F. Supp. 869 (S.D. Ohio 1994). In addition to the traditional medical monitoring, Plaintiffs seek a remedy uniquely crafted to this case, the creation of a prescription monitoring program. Such a program will permit doctors to identify persons developing symptoms of the disease of narcotics' addiction.

Purdue itself acknowledges that addiction to OxyContin is a disease, with many recognizable attributes.[3] As stated by Purdue in the PDR:

[3] Because Defendants acknowledge that addiction to OxyContin is in itself a disease, Plaintiffs' request for medical monitoring to detect and prevent addiction is distinguishable from the relief requested in the cigarette litigation, in which the plaintiffs sought monitoring of people addicted to cigarettes to see if they were at increased risk of other diseases, such as lung cancer. Because of the difficulty in identifying class members, the numbers of different brands of cigarettes sold, the different warnings given over the many years, and the fact that the plaintiffs' theory required addiction to be proven in order to establish an increased risk of other diseases, the Court declined to certify the class. *See Barnes v. Amer. Tobacco*, 161 F.3d 127, 143-146.) This holding is distinguishable from Plaintiffs' request herein, because Plaintiffs seek to prevent OxyContin addiction itself, which is conceded to be a disease, to which Plaintiffs have been exposed unreasonably by Defendants' wrongful conduct.

> Drug addiction is characterized by compulsive use, use for non-medical purposes, and continued use despite harm or risk of harm. Drug addiction is a treatable disease, utilizing a multi-disciplinary approach, but relapse is common.
>
> "Drug seeking" behavior is very common in addicts and drug abusers. Drug-seeking tactics include emergency calls or visits near the end of office hours, refusal to undergo appropriate examination, testing or referral, repeated "loss" of prescriptions, tampering with prescriptions and reluctance to provide prior medical records or contact information for other treating physician(s). "Doctor shopping" to obtain additional prescriptions is common among drug abusers and people suffering from untreated addiction.

Ex. 1 at p.2853. Because patients suffering from prescription drug addiction typically begin by seeking additional prescriptions, prescription monitoring programs have been created in many states to quickly identify persons developing drug dependence or addiction. Through these programs, patients seeking refills before the scheduled date, patients seeking multiple prescriptions for the product, or patients seeking new doctors after discontinuation of the prescription by their prior doctor, can be identified and helped.

The effectiveness of these programs is well recognized by experts in the field of addiction. In fact, health care providers constitute 98% of those accessing prescription monitoring systems. (See Ex. 3.) Accordingly, only 2% of those accessing prescription monitoring systems is done so by law enforcement. *Id.* Thus, contrary to Defendants' sophistic argument, Plaintiffs are not attempting to criminalize their own class members. To the contrary, Plaintiffs are seeking to establish a public health program which will identify and protect those persons at risk of harm, before their lives are ruined by the addictive properties of Defendants' product.

Defendants assert that Prescription Monitoring Programs are only a means of assisting law enforcement in criminal prosecution. Defendants cite to an article co-authored by one of Plaintiffs' experts, John Eadie, as support for this assertion. Yet, Defendants cite Mr. Eadie's article in a completely misleading manner. Defendants suggest that Mr. Eadie's article finds the core purpose of Prescription Monitoring Programs to be "investigations and enforcement"

(Defendants' Response Brief, p.43). However, Defendants deliberately omit the first three objectives of a Prescription Monitoring Program delineated in Mr. Eadie's article, namely:

1) Education and information;

2) Public health initiatives;

3) Early intervention and prevention of diversion.

Pain Management and Prescription Monitoring, 23 J. Pain & Symptom Mgmt., No. 3, (2002), at p.233 (attached as Ex. 4). These three objectives are specifically in line with Plaintiffs' objectives herein.

Purdue itself recognizes the utility of prescription monitoring programs. Indeed, Purdue agreed to pay $2 million to fund such a program in the state of Florida, in exchange for the state's dismissal of a criminal action against Purdue. (See Statement from Florida Attorney General, Ex. 5). Eighteen states now have some form of such programs, with more in the planning stage, but they are expensive to initiate, and expensive to maintain. C. Richard Allen, Deputy Director of the Drugs and Narcotics Agency, State of Georgia, writes in a letter concerning the status of the effort to obtain a prescription monitoring program in his state:

> We have a very serious problem in this state with OxyContin addiction and abuse….there have been numerous deaths and several suicides of people addicted to OxyContin. Some of these victims have been well educated, members of prominent families. They became addicted to OxyContin, believed there was no other way out, and they killed themselves, leaving letters explaining why they had done what they had done.
>
> Even a relative of a high ranking, elected state official became addicted to OxyContin. I was personally sent to investigate this case and determined where the person was obtaining their drugs. When the state official asked what could be done to help alleviate the OxyContin problem we explained what an electronic monitoring program could accomplish. He expressed sincere interest in helping us to obtain funding to start such a program in Georgia.
>
> However since that time, the state has had serious budget problems, and there has been no extra money to allocate for any type of new programs….

See Ex. 6

Furthermore, the current programs do not provide access to data across state lines. Thus the programs are ineffective for deterrent in border regions, such as Cincinnati, where persons can easily cross from state to state. The remedy proposed by Plaintiffs, to initiate and improve statewide monitoring programs, under supervision of the Court, and to implement nationwide prescription monitoring which permits access from state to state, promotes a remedy recognized by experts in the field to provide important screening and deterrence, and improves upon existing programs by providing access to information across state lines.

The DEA, along with various other governmental agencies, have recommended the establishment or expansion of prescription monitoring programs throughout the states. See Ex. 7, indicating a joint endorsement of prescription monitoring programs by the DEA as well as Purdue. The DEA as well as Purdue similarly endorsed prescription monitoring programs during a Congressional Subcommittee Hearing on OxyContin, December 11, 2001. At the hearing Dr. Paul Goldenheim on behalf of Purdue Pharma stated:

> Prescription monitoring programs ("PMPs") would help. The PMPs in Kentucky and Nevada can serve as useful models. PMPs can reduce doctor shopping and diversion from good medical practices by giving physicians a way to identify patients who are receiving controlled substances from other doctors. Purdue supports the adoption by all states of prescription monitoring programs meeting appropriate standards….Purdue is prepared to utilize its resources to explain the benefits of such a system to physicians and to gain support for such legislation from the medical community.

See Ex. 8

Asa Hutchinson, Administrator of the Drug Enforcement Administration, also testified that the DEA had initiated meetings with the National Alliance for Model State Drug Laws to lend their assistance in the establishment of state prescription monitoring programs. Id.

At the hearing, US Representative Frank Wolf, Chairman of the Subcommittee, stated in his opening remarks:

> I hope we can bring a focus [sic] today [sic] working toward a quick, meaningful, and successful solution. One solution might be to require that all states institute prescription monitoring programs. I understand that 18 states have prescription

> monitoring programs now. We will be interested in hearing more from the panelists about the benefit of those and perhaps even a nationwide system.

Id.

In addition, Defendants have argued that efforts such as prescription monitoring programs will keep certain patients from receiving the medication they need for pain. However, Alan Must, Executive Director, State Government and Legislative Affairs for Purdue indicated his company's support for state prescription monitoring programs on October 24, 2002 by stating, "Purdue Pharma has seen no chilling effect of PMPs, and is promoting the adoption of electronic monitoring programs." (See Ex. 9, p 12.)[4]

Moreover, because the government and addiction experts recognize the importance of prescription monitoring programs to prevent drug addiction and abuse, the remedy sought by Plaintiffs herein, like the request for echocardiograms in fen-phen, is one of proven efficacy recommended by experts in the field. (*Cf. In re: Rezulin Products Liability Litigation*, 210 F.R.D. 61,73 (S.D.N.Y. 2002) (noting that no major medical organization, public health agency or professional medical society recommended medical monitoring for Rezulin users); *In re: Propulsid Products Liability Litigation*, 208 F.R.D. 133, 147 (E.D. La. 2002) (noting neither FDA, nor any major medical association has recommended a program of medical monitoring for Propulsid users.) By being prescribed OxyContin for chronic use, each Plaintiff is placed at a risk of addiction to narcotics, and thus exposed to developing a serious and life-threatening disease. Reasonable tests exist to screen for this disease, in this case, tests that consist of monitoring product use to identify excess prescriptions. Just as plaintiffs exposed to radiation are at risk of developing cancer, and could be identified by appropriate medical screening (*Day v. NLO*, 851 F. Supp. 869, 879-880 (S.D.O.1994), or plaintiffs exposed to fen-phen were at risk of heart valve disease, and could be identified by echocardiograms (*In re: Diet Drugs Products Liability Litigation*, 1999 WL 673066 (E.D. Pa.), or plaintiffs implanted with defective heart valves

[4] Remarks given at the National Association of State Controlled Substances Authorities 18th Annual Educational Conference, written conference summary.

were at increased risk of paravalvular leak which could be identified by monitoring for specific side effects, (*In re: St. Jude*, 2003 WL 1589527 at *1), plaintiffs exposed to OxyContin are at significant risk of developing the disease of narcotics addiction, and may be identified through early detection via prescription monitoring programs. Under the particular facts of this case, prescription monitoring is recognized as the best remedy to identify those at risk of harm, and to protect and treat them at the earliest stage of their disease.

The medical monitoring program requested by Plaintiffs can be used to educate general practitioners and others unfamiliar with prescriptions for high doses of narcotics on the factors to consider in managing patients.[5] Experts in pain management advocate such programs, which include contracts with patients, limits on prescriptions (usually one month), mandatory office visits for refills, use of tamper-proof prescription pads, and other such devices, designed to prevent and avoid addiction to narcotics. Once again, Purdue recognizes and promotes the utility of such programs. (See Ex. 8.) Creation of a medical monitoring and education program, which would instruct physicians on the proper use and monitoring of patients given OxyContin prescriptions for chronic pain, is an important equitable remedy which is even advocated by Defendant itself. See Id. Purdue has also paid for tamper proof prescription pads in various regions of the country. Id.

Finally, Plaintiffs' request for a research program to accurately determine the true risk of addiction from chronic use of OxyContin clearly addresses an important need, inasmuch as Purdue concedes that it has never bothered to perform such studies. An accurate determination of the true risk of developing a disease, in this case drug addiction, from use of a

[5] Currently Purdue is attempting to place a new drug on the market called Palladone. Palladone is a high dose, extended release formulation containing hydromorphone. This drug is even more potent than OxyContin; whereas OxyContin was twice as potent as morphine, Palladone is 10 times as potent as morphine. Laura Nagel, Deputy Assistant Director of the Office of Diversion Control of the DEA wrote a letter to the FDA stating that the DEA believes that "It is highly likely that this particular drug molecule with a past history of widespread abuse and diversion may cause a larger public health hazard than that of OxyContin." Ms. Nagel also stated that the active ingredient in Palladone is identical to that in Dilaudid, "the drug of choice for addicts." Perhaps, unfortunately, Palladone will also create a population of patients who would be greatly benefited by having prescription monitoring programs in place.

prescription drug, should be born by the drug companies deriving profits from product sales, not by the victims who relied upon Defendants' claim that development of the disease is "rare." Neither informed consent nor proper evaluation of the risk/benefit ratio can occur when the degree of risk of a known disease caused by the product remains undisclosed. Research programs are an important aspect of equitable relief for claimants exposed to dangerous products. See *In re: St. Jude*, 2003 WL 1589527 at *2; *In re: Diet Drugs*, 1999 WL 673066 at *4. The necessity and utility of such a program under the present circumstances is well established.

IV. Plaintiffs Propose a Cohesive and Manageable Class that Satisfies the Requirements of Rule 23.

A. Defendants' Standing Argument is Without Merit.

In order to establish Article III standing, Plaintiffs must demonstrate only an "injury-in-fact," a causal connection between the injury-in-fact and the Defendants' conduct, and a likelihood that a favorable decision will redress the injury. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 559-60 (1992). The named plaintiffs for the national medical monitoring class have established that they received a prescription for OxyContin by their medical care provider, and that they have been placed at risk of harm of addiction due to Defendants' wrongful conduct. The increased risk of contracting a disease constitutes an "injury-in-fact." See *Friends for All Children v. Lockheed Aircraft Corp*., 746 F.2d 816, 825 (D.C. App. 1984), *In re: Propulsid,* 208 F.R.D. 133, 139-140 (E.D. La., 2002) ("courts have long recognized that an increased risk of harm, which the plaintiff alleges, is an injury in fact.") Plaintiffs further allege that their injury was caused by Defendants' wrongful conduct, and that the screening procedure of medical and prescription monitoring will redress their injuries. As such, Plaintiffs have established Article III standing. See *In re: St. Jude*, 2003 WL 1589527 at *11; *In re: Propulsid*, 208 F.R.D. 133, 139-140 (E.D. La, 2002).

B. Plaintiffs have Established Numerosity.

Since its initial product approval in 1995, OxyContin has leaped to the 13th best selling prescription drug in the United States, with total sales in 2002 of $1,588,489,000.00 for 6,388,000 units, or prescriptions. (See Ex. 10.) In 2001, OxyContin sales exceeded $1,450,000,000.00, with over 7,200,000 prescriptions sold. (Id.) Clearly, with millions of Americans being prescribed OxyContin, and thus at risk of developing addiction, plaintiffs have established numerosity. See *In re: Diet Drugs*, 1999 WL 673066 at *8, "millions of prescriptions for Redux and Pondimin were written. Joinder or hundreds of thousands, if not millions, of claimants would certainly qualify as impracticable; *Howland v. Purdue Pharma*, 2003 WL 21637968 at *4. ("Over one million prescriptions for OxyContin have been filled in retail pharmacies in this state from June 1998 to December 2001. This evidence is sufficient to establish the impracticality of joinder against Purdue and Abbott.")

C. Plaintiffs have Established Commonality.

Plaintiffs seek certification under Rule 23(b)(1)(A) and Rule 23(b)(2) of a class action providing for equitable relief. Plaintiffs seek to prove that Defendants manufactured and marketed a defective product, which was unreasonably dangerous to consumers, and/or the risks outweighed the benefits, and/or Defendants failed to adequately warn of the products' risks. Plaintiffs also seek to prove that Defendants negligently manufactured, marketed and promoted the drug, and thereby exposed consumers to harm from their product, and that Defendants were unjustly enriched. As a result of Defendants' wrongful conduct, Plaintiffs and the class are at significantly increased risk of contracting the disease of narcotics' addiction, and are therefore in need of the equitable remedies of monitoring and research sought in the complaint, in order to provide early detection and treatment of this illness.

Therefore, the issue of predominance of individual issues over common issues does not arise in considering Plaintiffs' request for certification, because predominance is only a consideration in a Rule 23(b)(3) class. Instead, Plaintiffs need prove only that some common

questions of fact or law exist. "The commonality test 'is qualitative rather than quantitative, that is, there need be only a single issue common to all members of the class.'" *In re: American Medical Systems, Inc.*, 75 F.3d 1069, 1080 (6th Cir. 1996), citing Newberg, et al., *Newberg on Class Actions*, § 3-10 at 3-50 (3d ed. 1992.) Moreover, because Plaintiffs seek equitable relief in the form of screening persons exposed to OxyContin to detect and prevent addiction, and seek educational, research and prevention programs which Defendants concede to be effective, Plaintiffs' case does not present individual issues of proximate cause and damages found in many nationwide personal injury class action situations. For example, *American Medical Systems* involved a nationwide class for personal injury based upon several different models of medical devices manufactured by Defendant. The Court noted that unlike a toxic tort mass accident case, such as presented in *Sterling v. Velsicol Chem. Corp.*, 855 F.2d 1188 (6th Cir. 1988), nationwide medical device products liability cases "often *do* differ dramatically from individual to individual because there is no common cause of injury." *In re: American Medical Systems,* 75 F.3d at 1084. This analysis, however, has no applicability to Plaintiffs' claim herein, because Plaintiffs seek recovery to screen and protect from injury through medical and prescription monitoring, based on the common issue that they are all placed at significant risk of developing addiction due to their ingestion of this drug. Personal injury claims are not alleged, and thus variations in proof of personal injury are not at issue in this case.

The Sixth Circuit recognized in *American Medical Systems* that nationwide class actions in medical products cases can still be appropriate in specific situations, depending upon the facts presented. *Id*. at 1089. The Sixth Circuit cited with favor, the case of *In re: Copley Pharmaceutical, Inc*., 158 F.R.D. 485 (D. Wyo. 1994), in which the Court certified a nationwide personal injury class based on injuries claimed from a defective bronchodilator. *American Medical Systems*, 75 F.3d at 1089, n. 25 (noting that the Copley cased involved "'one product,' and that 'the common questions' were 'more straight forward than those in many product liability cases.'") In *Copley*, the Court certified the class on general issues of liability only, pursuant to

Rule 23(c)(4)(A), and severed individual issues of proximate cause and damages. *Copley*, 158 F.R.D. at 492. In affirming its certification order, the Court in *Copley* noted that many of the "nuances" of state law raised by Defendant as confounding factors were irrelevant to the facts at issue in the case. The Court also noted that the class could always be modified, if necessary, to remove certain states from the class if irresolvable complications arose. "Therefore, the Court is not intimidated by the parade of horribles presented by Defendant." *In re: Copley Pharmaceutical, Inc*. 161 F.R.D. 456 (D. Wyo. 1995).

Similarly, in *Telectronics*, the Sixth Circuit approved this Court's certification of a nationwide class action for trial purposes. (*See In re: Telectronics*, 137 F. Supp. 2d 985, 1000-1001, S.D.O. 2001.) The class included a medical monitoring subclass, two negligence subclasses (based on whether the state recognized a state of the art defense), and four strict liability subclasses. The strict liability subclasses distinguished between those states that permitted state of the art as a defense, and then had a further category based upon the state's definition of defective product. *In re: Telectronics*, 172 F.R.D. 271, 278-79 (S.D.O. 1997.) Because the Court recognized that some states require physical injury in order for an individual to recover medical monitoring, the Court divided the medical monitoring class into two subdivisions. *Id*. at 287. That management tool can also be utilized here, if need be. Most courts agree, however, as recently clarified in, *In re: West Virginia Rezulin Litigation*, -- S.E.2d -- 2003 WL 21518104 at *19 (W.Va., July 3, 2003) (attached hereto as Ex. 12), that physical injury is not required for a medical monitoring claim. Rather, "'[t]he 'injury that underlies a claim for medical monitoring – just as with any other cause of action sounding in tort – is the 'invasion of any legally protected interest.'" *Id.*, quoting *Bower v. Westinghouse Elec. Corp*., 206 W.Va.133, 140, 522 SE.2d 424, 431 (1999). Thus, many courts have certified nationwide medical monitoring class actions despite the variations in state laws which might arise on specific issues. *See, e.g., In re: Diet Drugs*, 1999 WL 673066 (E.D. Pa. 1999); *St. Jude*, 2003 WL 1589527.

As noted in the *Copley* opinion, the Court has the authority and discretion to modify any class certification order as the case progresses toward trial. *See*, Fed. R. Civ. P. 23(c)(1), "An order under this subdivision may be conditional, and may be altered or amended before the decision on the merits." Moreover, courts are encouraged to certify those issues which are susceptible to class-wide resolution. (See *Cent. Wesleyan College v. W. R. Grace & Co.*, 6 F.3d 177, 185 (4th Cir. 1993); *Robinson v. Metro-North Commuter Railroad Co.*, 267 F.3d 147 (2nd Cir. 2001), encouraging the use of Rule 23(c)(4)(A) to certify separate issues and thereby achieve judicial efficiencies.) Here, where Plaintiffs have defined their class and restricted their claims for relief to those which are readily susceptible to a class-wide resolution, the Court should promote judicial economy and act to protect the interests of Plaintiffs, by ordering class-wide relief which protects Plaintiffs from developing future injury.

Finally, Defendants' argument that Plaintiffs' claims are actually claims for monetary relief lacks merit. The remedies requested by Plaintiffs provide no monetary recovery to individual plaintiff. Instead, the resources recovered are for the general benefit of the class, under the administration of the court, to develop medical and prescription screening programs, to create educational and training programs for doctors, to provide tamper resistant prescription pads, and to perform research in the addictive effects of OxyContin. These remedies do not personally enrich any individual. The fact that it takes money to pay for the programs, does not render the programs themselves a form of compensatory damages to specific individuals. See *Day v. NLO*, 851 F.Supp. at 886 (noting that the use of the court's equitable powers to supervise and administer medical surveillance payments is highly appropriate).

D. Plaintiffs have Established Typicality.

Defendants' argue that class representatives are not typical of the putative class based on one legal theory: the plaintiffs' claims turn on individual facts. Defendants miss two important concepts. First, Plaintiffs' legal theories do not involve individual issues, and second, the law is well settled that the typicality requirement is satisfied even if there are factual distinctions

between the named plaintiffs and those of the class members. See *In re: Telectronics Pacing Systems*, 168 F.R.D. 203, 214 (S.D. Ohio 1996) (citations omitted). See also, *In re: St. Jude Medical, Inc. Silzone Heart Valves Products Liability Litigation,* 2003 WL 1589527, *3 (D. Minn.) ("(F)actual variation in the individual claims will not normally preclude class certification if the claim arises from the same event or course of conduct as in the class claims, and gives rise to the same legal or remedial theory" (citations omitted)). "When the claim arises out of the same legal or remedial theory, the presence of factual variations is normally not sufficient to preclude class treatment." *In re: West Virginia Rezulin Litigation,* 2003 WL 21518104, *13 (W Va.) (certifying medical monitoring class of West Virginia residents who ingested Rezulin).

Just as in the *Fen-phen* and *West Virginia Rezulin* cases, Plaintiffs' ingestion of OxyContin alone is the basis for their medical monitoring claims. Through conduct directed to all OxyContin users, not just to the individual class representatives, Defendants failed to warn about *any* addiction potential of their powerful narcotic, failed to perform *any* testing on the additive potential of OxyContin, defectively designed it to increase its addictive potential, and promoted it to ensure that OxyContin was prescribed frequently for non-acute, non-cancer related pain. Thus, although factual differences between the putative class members' claims and the class representatives' claims may exist, the legal theories are identical.

Defendants attempt to analogize this case to cigarette smoking cases, where courts found typicality lacking due to the multiple products, multiple defendants, and lengthy time periods involved. (See, e.g., *Barnes*, 161 F.3d at 143.) By contrast, Plaintiffs' claims herein involve one prescription narcotic manufactured and promoted by only two Defendants, for a very short time period [since 1995.] Defendants also argue that typicality is defeated because Plaintiffs continued to use OxyContin even after learning of the products' defects. This argument underscores Defendants' ignorance as to opioid drugs and the need for medical monitoring. Defendants are liable for failing to warn *before* Plaintiffs and the putative class began taking OxyContin. Plaintiffs needed to know before they were prescribed OxyContin for

their mild to moderate pain conditions that they would experience heroin-like withdrawal symptoms if they chose to even decrease their dosage. Defendants' position simplistically disregards that persons on opioids develop physical dependence and addiction, and cannot abruptly stop taking the product without suffering serious symptoms of withdrawal. Most patients need medical treatment, including supervised reductions of milligrams, use of alternative products such as methadone, or confinement to a detoxification clinic, to wean themselves from OxyContin. (See Ex. 11, p.2.)

Whether the named Plaintiffs succeed in weaning themselves off OxyContin due to its dangers, is not relevant to their appointment as class representatives, because at the time the complaint and certification motion was filed, each Plaintiff stated a valid claim for equitable relief. See *Holmes v. Pension Plan of Bethlehem Steel Corp*., 213 F.3d 124, 135-136 (3rd Cir. 2000.) Moreover, Defendants' argument that the claims of the representatives are not valid forces the Court to inappropriately analyze the merits of the class representatives claims, and is therefore inappropriate at this stage of the proceedings. *In Re: Copley,* 158 F.R.D. at 489.

E. Plaintiffs are Adequate Representatives and Have Engaged Competent and Experienced Counsel.

To be an adequate class representative, a named plaintiff must have common interests with the unnamed members of the class and must have sufficient interest in the outcome to ensure vigorous advocacy. *In re: Telectronics,* 172 F.R.D. 271, 281. Defendants rely on two distinguishable cases to assert that the Named Plaintiffs'[6] past history – not their current conduct in this litigation -- make them inadequate representatives.[7] However, the past misconduct of proposed class representatives is irrelevant to the issue of their adequacy. *See, e.g., Haywood v. Barnes*, 109 F.R.D. 568 (E.D. N.C. 1986) (court rejected defendants'

[6] As Defendants are well aware, Barbara Sawyers advised counsel that she is no longer able to act as class representative. Accordingly, all facts about Barbara Sawyers are irrelevant.

[7] Defendants also over dramatize the facts. Mr. Fantozzi's conviction, for example, occurred over 20 years ago when he was a college student and was found guilty of driving his friends away after they stole some beer from the local grocery store; Mr. Lester sold his OxyContin over four years ago; and Mr. Betleyoun had several traffic citations and one conviction for theft nearly three years ago.

contention that criminal records of several named plaintiffs made them inadequate representatives); *In re: Activision Securities Litigation*, 621 F.Supp. 415 (N.D. Cal. 1985) (neither criminal record nor lack of cooperation during deposition rendered named plaintiffs inadequate representatives); *Kleiner v. First Nat. Bank of Atlanta*, 97 F.R.D. 683 (N.D. Ga. 1983) (named plaintiff's adequacy not undermined by defendant's affidavits alleging past criminal behavior).

In *Weisman v. Darneille*, 78 F.R.D. 669, (S.D.N.Y. 1978), the chief case relied upon by Defendants, the plaintiff was held to be an inadequate class representative where the plaintiff was convicted of violating the very statute he invoked in his securities litigation. Moreover, the plaintiff had committed perjury during his deposition in the case. In the only other case cited by Defendant, *Hall v. Nat'l Recovery Systems*, 1996 WL 467512 (M.D. Fla.), an unreported decision, the plaintiff was held to be an inadequate representative where he was in and out of jail for major periods of his adult life, his drivers license was suspended for failing to secure insurance coverage, and there were currently three warrants out for his arrest. Significantly, the *Hall* court suggested that the allegations against Hall individually may not have been enough to defeat adequacy of representation, but taken together, the Court felt the named plaintiff would lack credibility at trial. *Id.*

Here, there are no current allegations of dishonesty in any of the class representatives. Rather, to date, the class representatives have acted promptly and cooperatively to provide necessary information for this case. Each class representative timely provided prescription information documenting their use of OxyContin. And in the spirit of cooperation, even though Plaintiffs do not assert personal injury claims, the Named Plaintiffs agreed to provide full medical authorizations to Defendants, and did so in less than 7 business days from the time the authorizations were requested by Defendants.[8] Thus the class members vigorous

[8] In fact, it should be noted that Defendants failed to provide HIPAA compliant authorizations until June 30, 2003. Counsel immediately disseminated and obtained return authorizations within two weeks.

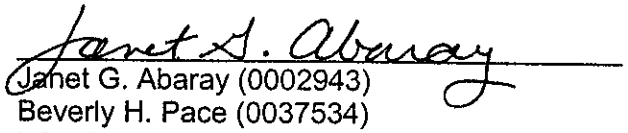
representation has been established. See, e.g., *Mularkey, et al. v. Holsum Baker, Inc.*, 120 F.R.D. 118, 121-122 (D. Ariz. 1998) (Plaintiff is adequate representative despite having pled guilty of aiding and abetting theft by a bank employee, failing to file his most recent tax returns, and for failure to pay sales tax on his business for over two years. Court noted that the more relevant question is whether Plaintiff will vigorously represent the interests of the class.) Furthermore, as the Court in *Mularkey* noted, if a class representative "proves wanting" in the future, he can be decertified as a class representative at that time." *Id.* at 122.

Defendants' additional argument -- that Counsel for Plaintiffs cannot represent a medical monitoring class because they also represent individual injured victims – aggressively misconstrues the law. Only if a conflict exists between members of the medical monitoring class and personal injury plaintiffs would there be a need to have separate counsel. Such a conflict could arise if counsel represented opposing parties in regard to allocation of limited settlement proceeds. (See *Amchem v. Windsor,* 521 U.S. 591 (1997), finding a conflict where counsel, who represented both present and future claimants, negotiated a single settlement fund which provided more favorable payments to one group.) Absent such an allocation issue, no conflict exists between tort victims who assert claims against common defendants in mass tort cases. See *St. Jude*, 2003 WL 1589527 (simultaneously certifying medical monitoring and personal injury class) *In re: Diet Drugs*, 1999 WL 673066 at *9 (approving the appointment of class counsel based in part upon the fact that they were also members of the Plaintiffs Management Committee for personal injury cases in the multidistrict proceedings, and were thus "experienced and qualified" in handling mass tort cases.)

V. Conclusion

For the foregoing reasons, Plaintiffs respectfully request that this Honorable Court grant Plaintiffs' Motion for Class Certification.

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that a true and accurate copy of the foregoing was filed with the Clerk of Court using the CM/ECF system and was served via regular U.S. Mail and/or via electronic mail by the Clerk on this, the 11th day of September, 2003 on the following:

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